

Appl. No. 10/791,469
Amdt. dated September 8, 2010
Amendment under 37 CFR 1.116 Expedited Procedure
Examining Group 3773

PATENT

Amendments to the Drawings:

The attached sheets of drawings include formal replacement sheets of the informal drawings as filed.

Attachment: Replacement Sheet

REMARKS/ARGUMENTS

This paper is responsive to the Final Office Action mailed June 8, 2010. Claims 1-8, 10-16, 18-24, 33-40 and 55-84 were pending before submission of this paper. Claims 1-8, 10-16, 18-24, 33-40, and 55-84 stand rejected. Specifically, claims 74-84 stand rejected as allegedly being directed to an invention that is independent or distinct from the invention originally claimed. Claims 1, 10-16, 18-24, 33-36, and 38-40 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kugler et al. (US 6,129,756) (hereinafter “Kugler”) in view of Elliot (US 2003/0236567) (hereinafter “Elliot”), in view of Greenberg (US 2004/0193254) (hereinafter “Greenberg”), and in further view of Hyodoh et al. (US 6,409,750) (hereinafter “Hyodoh”). Claims 2-7, 37, 55-58, and 60-73 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kugler in view of Elliot, Greenberg, and Hyodoh, as applied to the claims above, and in further view of Vrba (US 6,168,621) (hereinafter “Vrba”). Claims 8 and 59 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kugler in view of Elliot, Greenberg, Hyodoh, and Vrba, as applied to the rejections above, and in further view of Austin et al. (US 6,945,994) (hereinafter “Austin”). Applicants respectfully disagree. Claims 1, 33, 36, 55, 57, 60, 61, 63, and 64 have been amended. Support for all amended claims can be found in the specification. No new matter has been added by these amendments. Reconsideration of the claims in view of the amendments and the following remarks is respectfully requested.

I. Examiner Interview

A telephone interview was conducted with Examiner Erezo on Wednesday, July 21, 2010 at 2:00 PM Eastern Time. The undersigned attorney represented Applicants in the interview. Proposed amendments were discussed in detail. In the interview, proposed amendments to claims 55 and 64 were discussed. Although no definite agreement with respect to allowance was reached, Examiner Erezo agreed that the proposed amendments to claims 55 and 64 overcome the present rejection. Examiner Erezo graciously offered several suggestions

regarding claims 1 and 33. Applicants appreciate Examiner Erez's suggestions and present this response accordingly.

II. Amendment to the Drawings

Replacement drawings are submitted herewith. During the interview, Examiner Erez mentioned that the originally-filed drawings should be replaced with formal drawings. Accordingly, the new drawings are merely formal replacements of the previous informal drawings and are substantially similar to the previous informal drawings. As a result, the formal drawings do not introduce new matter.

III. Amendment to the Specification

Paragraph 53 is amended to recite a "coupling member 410," an example of which is shown in Figure 10, to provide an explicit recitation of the reference numeral "410." Accordingly, this amendment does not introduce new matter.

IV. Claims 1, 10-16, 18-24, 33-36, and 38-40 Are Allowable Under 35 U.S.C. § 103(a) Over Kugler in View of Elloit, Greenberg, and Hyodoh

Claims 1, 10-16, 18-24, 33-36, and 38-40 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kugler in view of Elloit, Greenberg, and Hyodoh. Applicants respectfully disagree.

With regard to rejections under 35 U.S.C. § 103, the Examiner must provide evidence which as a whole shows that the legal determination sought to be proved (*i.e.*, the reference teachings establish a *prima facie* case of obviousness) is more probable than not. M.P.E.P. § 2142. Accordingly, "the key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious." M.P.E.P. § 2142; *see KSR International Co. v. Teleflex, Inc.*, 550 U.S.398, 82 USPQ 2d 1385, 1395-97 (2007).

A. Independent Claim 1

Applicants' claim 1, as amended, recites:

1. (Currently Amended) A stent-graft device for treating an abdominal aortic aneurysm, the stent-graft device comprising:
 - at least one stent member comprising at least one of a self-expanding stent member and a balloon-expandable stent member;
 - at least one tubular graft member coupled with the at least one stent member, the tubular graft member having a proximal end and at least one distal end, said at least one tubular graft member, once deployed, comprising a main graft member toward the proximal end of the tubular graft member and at least one sinusoidal leg member toward the distal end of the tubular graft member relative to the main graft member, each of said at least one sinusoidal leg member being coupled with the main graft member, said at least one sinusoidal leg member having shape memory biasing at least one sinusoidal leg member toward a sinusoidal shape such that, once deployed, said at least one sinusoidal leg member is elongatable with elongation of the abdominal aortic aneurysm; and
 - at least one skirt graft member coupled with at least one of the stent member and the tubular graft member at or near the proximal end of the tubular graft member and extending toward the distal end,
wherein the skirt graft member is configured to be placed in contact with the inner wall of the aortic aneurysm when the stent-graft device is implanted adjacent to the abdominal aortic aneurysm.

Such subject matter as recited by amended claim 1 is not disclosed, taught, or suggested by Kugler, Elloit, Greenberg, or Hyodoh, either individually or in combination.

Claim 1 recites "at least one sinusoidal leg member having shape memory biasing said at least one sinusoidal leg member toward a sinusoidal shape." This feature was added in the last response. The Office action cites to Hyodoh to demonstrate that shape memory in stents is well known in the art. However, even if shape memory material in stents was well in the art, our claim recites more than just shape memory material in a stent. In particular, our claim specifically recites that the shape memory biases the sinusoidal leg member toward a sinusoidal shape. Hyodoh does not teach this feature. For instance, looking at Hyodoh's Figure 28, the shape memory material biases the leg of a stent into a rigid, cylindrical shape. In addition, Hyodoh describes the use of shape memory for a completely different purpose than biasing the

leg to a particular curve. Specifically, at the end of the paragraph spilling onto column 21, Hyodoh teaches that the purpose of the shape memory is to prevent outer compression. Therefore, Hyodoh does not teach or suggest “at least one sinusoidal leg member having shape memory biasing said at least one sinusoidal leg member toward a sinusoidal shape.”

Furthermore, Applicants amended claim 1 to recite, that the shape memory biases a sinusoidal leg member toward a sinusoidal shape “such that, once deployed, said at least one sinusoidal leg member is elongatable with elongation of the abdominal aortic aneurysm.” This amendment is supported at least by Figures 4-6 in the application as filed. Greenberg does not teach or suggest at least such subject matter. For example, the Office Action at page 5 cites to Figures 8a-8d of Greenberg for a sinusoidal leg member. During the interview, Examiner Erez confirmed that he equates the branch 142 with a “sinusoidal leg member” as recited in claim 1. However, even assuming *arguendo* that the branch 144 shown in Figures 8a-8d of Greenberg is a sinusoidal leg member, the branch 144 of Greenberg is not configured “such that, once deployed, said at least one sinusoidal leg member is elongatable with elongation of the abdominal aortic aneurysm.” Looking to Figure 15 of Greenberg, for example, an embodiment of Greenberg’s device is shown as deployed. The branch 408 (similar to the branch 144 in Figures 8a-8d) is shown as extending from the iliac artery 405 to the hypogastric artery 406, that is, away from the aortic aneurysm 402. Accordingly, even if the branch 408 is elongatable, elongation of the branch 408 does not elongate with elongation of the aortic aneurysm 402.

Indeed, Examiner Erez agreed during the interview that Greenberg does not show this feature and that an amendment to recite this feature would overcome the present rejection. Therefore, because the cited references alone or in combination fail to teach or suggest each and every element of the claimed invention, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a) over Kugler, Elliot, Greenberg, and Hyodoh. Applications respectfully request withdrawal of the § 103(a) rejection and allowance of independent claim 1 and the claims dependent thereon.

B. Independent Claim 33

Applicants' claim 33, as amended, recites:

33. A stent-graft device for treating an abdominal aortic aneurysm, the stent-graft device comprising:
a proximal stent member for coupling the stent device with the abdominal aorta proximal to the aneurysm;
at least one distal stent member for coupling the stent device with a blood vessel distal to the aneurysm; and
at least one graft member coupled with and extending between the proximal stent member and the at least one distal stent member, at least a portion of the graft member being pre-shaped with at least one bend having shape memory such that, upon deployment, said at least a portion of the graft member is biased to have an elongatable sinusoidal shape,
wherein the sinusoidal portion is configured to be positioned at least partly within the abdominal aortic aneurysm when the stent-graft device is implanted adjacent to the abdominal aortic aneurysm such that the stent graft device is elongatable with elongation of the abdominal aortic aneurysm.

Subject matter as recited by amended claim 33 is not disclosed, taught, or suggested by Kugler, Elloit, Greenberg, or Hyodoh, either individually or in combination.

Applicants respectfully submit that claim 33 is allowable at least for reasons discussed above in connection with claim 1. For example, claim 33 recites "being pre-shaped with at least one bend having shape memory such that, upon deployment, said at least a portion of the graft member is biased to have an elongatable sinusoidal shape." Therefore, at least for reasons similar to those discussed above, Applicants respectfully submit that the cited references do not anticipate claim 33.

Claim 33 recites that "the graft member is biased to have an elongatable sinusoidal shape" and "the stent graft device is elongatable with elongation of the abdominal aortic aneurysm." However, the cited references do not show this feature, individually or in combination. For example, the cylindrical trunk 42 in Greenberg Figure 3a is not elongatable. The portion of the graft inside the abdominal aortic aneurysm in Greenberg Figure 15 is also not elongatable.

Because the cited references alone or in combination fail to teach or suggest each and every element of the claimed invention, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a). Applications respectfully request withdrawal of the § 103(a) rejection and allowance of independent claim 33 and the claims dependent thereon.

C. Dependent Claims 10-16, 18-24, 34-36, and 38-40

Claims 10-16, 18-24, 34-36, and 38-40 each depend from independent claims 1 or 33. Accordingly, Applicants respectfully submit that claims 10-16, 18-24, 34-36, and 38-40 are allowable at least for depending from an allowable independent claim. Consequently, the rejections of claims 10-16, 18-24, 34-36, and 38-40 are rendered moot by above amendments and remarks. Nevertheless, Applicants respectfully submit that at least some of claims 10-16, 18-24, 34-36, and 38-40 additionally recite patentable subject matter not taught or otherwise rendered obvious by Kugler, Elloit, Greenberg, or Hyodoh, either individually or in combination. Therefore, Applicants respectfully submit that claims 10-16, 18-24, 34-36, and 38-40 are allowable under 35 U.S.C. § 103 over Kugler, Elloit, Greenberg, and Hyodoh. Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103.

V. Claims 2-7, 37, 55-58, and 60-73 Are Allowable Under 35 U.S.C. § 103(a) Over Kugler in View of Elliot, Greenberg, Hyodoh, and Vrba

Claims 2-7, 37, 55-58, and 60-73 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kugler in View of Elliot, Greenberg, Hyodoh, and Vrba.

A. Independent Claim 55

Applicants' claim 55, as amended, recites:

55. A stent-graft device for treating an abdominal aortic aneurysm, the stent-graft device comprising:
at least one stent member comprising a plurality of expandable members coupled together circumferentially to form a cylinder, some of the expandable members that are coupled together circumferentially comprising a self-expanding

material others of the expandable members comprising a balloon-expandable material; and

at least one tubular graft member coupled with the at least one stent member, the tubular graft member having a proximal end and at least one distal end, wherein the at least one stent member is configured to anchor the tubular graft member in an artery selected from the aorta and an iliac artery.

Subject matter as recited by amended claim 55 is not disclosed, taught, or suggested by Kugler, Elliot, Greenberg, Hyodoh, or Vrba, either individually or in combination. For example, Examiner Erezo, during the aforementioned interview, agreed that at least the following elements are not taught or otherwise rendered obvious pursuant to 35 U.S.C. § 103 by the cited art: "...at least one stent member comprising a plurality of expandable members coupled together circumferentially to form a cylinder, some of the expandable members that are coupled together circumferentially comprising a self-expanding material others of the expandable members comprising a balloon-expandable material..." Accordingly, Applicants respectfully request withdrawal of the rejection of claim 55 under 35 U.S.C. § 103 over Kugler in View of Elliot, Greenberg, Hyodoh, and Vrba.

B. Independent Claim 64

Applicants' claim 64, as amended, recites:

64. A stent-graft device for treating an abdominal aortic aneurysm, the stent-graft device comprising:

at least one stent member comprising a self-expanding stent layer and a balloon-expandable stent layer, the self-expanding stent layer and the balloon-expandable stent layer being laminated to one another radially from a central axis of the stent member; and

at least one tubular graft member coupled with the at least one stent member, the tubular graft member having a proximal end and at least one distal end, wherein the at least one stent member is configured to anchor the tubular graft member in an artery selected from the aorta and an iliac artery.

Subject matter as recited by amended claim 64 is not disclosed, taught, or suggested by Kugler, Elliot, Greenberg, Hyodoh, or Vrba, either individually or in combination.

For example, Examiner Erezo, during the aforementioned interview, agreed that claim 64, as currently amended, is not taught or otherwise rendered obvious pursuant to 35 U.S.C. § 103 by the cited art. For example, Examiner Erezo, during the aforementioned interview, agreed that at least the following elements are not taught or otherwise rendered obvious pursuant to 35 U.S.C. § 103 by the cited art: "...at least one stent member comprising a self-expanding stent layer and a balloon-expandable stent layer, the self-expanding stent layer and balloon-expandable stent layer being laminated to one another radially from a central axis of the stent member..."

Applicants respectfully request withdrawal of the rejection of claim 64 under 35 U.S.C. § 103 over Kugler in View of Elliot, Greenberg, Hyodoh, and Vrba.

C. Dependent Claims 2-7, 37, 56-58, 60-63, and 65-73

Claims 2-7, 37, 56-58, 60-63, and 65-73 each depend from independent claims 1, 33, 55, or 64. Accordingly, Applicants respectfully submit that claims 2-7, 37, 56-58, 60-63, and 65-73 are allowable at least for depending from an allowable independent claim. Consequently, the rejections of claims 2-7, 37, 56-58, 60-63, and 65-73 are rendered moot by above amendments and remarks. Nevertheless, Applicants respectfully submit that at least some of claims 2-7, 37, 56-58, 60-63, and 65-73 additionally recite patentable subject matter not taught or otherwise rendered obvious by Kugler, Elliot, Greenberg, Hyodoh, and Vrba, either individually or in combination. Therefore, Applicants respectfully submit that claims 2-7, 37, 56-58, 60-63, and 65-73 are allowable under 35 U.S.C. § 103 over Kugler, Elliot, Greenberg, Hyodoh, and Vrba. Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103.

VI. Claims 8 and 59 Are Allowable Under 35 U.S.C. § 103(a) Over Kugler in View of Elliot, Greenberg, Hyodoh, Vrba, and Austin

Claims 8 and 59 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kugler in View of Elliot, Greenberg, Hyodoh, Vrba, and Austin.

Claims 8 and 59 each depend from independent claims 1 or 55. Accordingly, Applicants respectfully submit that claims 8 and 59 are allowable at least for depending from an

allowable independent claim. Consequently, the rejections of claims 8 and 59 are rendered moot by above amendments and remarks. Nevertheless, Applicants respectfully submit that at least some of claims 8 and 59 additionally recite patentable subject matter not taught or otherwise rendered obvious by Kugler, Elliot, Greenberg, Hyodoh, Vrba, and Austin, either individually or in combination. Therefore, Applicants respectfully submit that claims 8 and 59 are allowable under 35 U.S.C. § 103 over Kugler, Elliot, Greenberg, Hyodoh, Vrba, and Austin. Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103.

VII. Amendment To The Claims

Unless otherwise specified or addressed in the remarks section, amendments to the claims are made for purposes of clarity, and are not intended to alter the scope of the claims or limit any equivalents thereof. The amendments are supported by the specification and do not add new matter. In addition, by focusing on specific claims and claim elements in the discussion above, Applicants do not imply that other claim elements are disclosed or suggested by the references. In addition, any characterizations of claims and/or cited art are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by another prosecution. Accordingly, reviewers of this or any child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present disclosure.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

Further, the Commissioner is hereby authorized to charge any additional fees or credit any overpayment in connection with this paper to Deposit Account No. 20-1430.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

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